

We claim:

1. A pharmaceutical composition comprising a porous matrix formed of a hydrophilic or hydrophobic excipient and microparticles of a drug,
 

wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and

wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .
2. The pharmaceutical composition of claim 1 comprising between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.
3. The pharmaceutical composition of claim 1 comprising between about 5 and 60% drug.
4. The pharmaceutical composition of claim 1 comprising one or more hydrophobic or hydrophilic excipients selected from the group consisting of polymers, amino acids, sugars, preservatives, wetting agents, tonicity agents, pegylated excipients, and combinations thereof.
5. The pharmaceutical composition of claim 1 wherein the excipient is hydrophobic or hydrophilic amino acid.
6. The composition of claim 1 wherein the drug is a low aqueous solubility drug.
7. The composition of claim 1 wherein the drug is a low aqueous solubility drug, wherein the porous matrix upon contact with an aqueous medium yields microparticles having a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and
 

wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ .
8. The composition of claim 1 wherein the drug is selected from the

group consisting of albuterol, adapalene, doxazosin mesylate, mometasone furoate, ursodiol, amphotericin, enalapril maleate, felodipine, nefazodone hydrochloride, valrubicin, albendazole, estrogens conjugated, medroxyprogesterone acetate, nicardipine hydrochloride, zolpidem tartrate, amlodipine besylate, ethinyl estradiol, omeprazole, rubitecan, amlodipine besylate/ benazepril hydrochloride, etodolac, paroxetine hydrochloride, paclitaxel, atovaquone, felodipine, podofilox, paricalcitol, betamethasone dipropionate, fentanyl, pramipexole dihydrochloride, Vitamin D<sub>3</sub> and related analogues, finasteride, quetiapine fumarate, alprostadil candesartan, cilxetil, fluconazole, ritonavir, busulfan, carbamazepine, flumazenil, risperidone, carbamazepine, carbidopa/ levodopa, ganciclovir, saquinavir, amprenavir, carboplatin, glyburide, sertraline hydrochloride, rofecoxib carvedilol, halobetasolpropionate, sildenafil citrate, celecoxib, chlorthalidone, imiquimod, simvastatin, citalopram, ciprofloxacin, irinotecan hydrochloride, sparfloxacin, efavirenz, cisapride monohydrate, lansoprazole, tamsulosin hydrochloride, mofafinil, azithromycin, clarithromycin, letrozole, terbinafine hydrochloride, rosiglitazone maleate, diclofenac sodium, lomefloxacin hydrochloride, tirofiban hydrochloride, telmisartan, diazepam, loratadine, toremifene citrate, thalidomide, dinoprostone, mefloquine hydrochloride,trandolapril, docetaxel, mitoxantrone hydrochloride, tretinoin, etodolac, triamcinolone acetate, estradiol, ursodiol, nelfinavir mesylate, indinavir, beclomethasone dipropionate, oxaprozin, flutamide, famotidine, nifedipine, prednisone, cefuroxime, lorazepam, digoxin, lovastatin, griseofulvin, naproxen, ibuprofen, isotretinoin, tamoxifen citrate, nimodipine, amiodarone, and alprazolam.

9. The composition of claim 1 wherein the drug is water-soluble.

10. The composition of claim 1 wherein the drug is selected from the group consisting of ceftriaxone, ketoconazole, ceftazidime, oxaprozin, albuterol, valacyclovir, urofollitropin, famciclovir, fluticasone, budesonide, flutamide, enalapril, mefformin, itraconazole, buspirone, gabapentin, fosinopril, tramadol, acarbose, lorazepam, follitropin, glipizide, omeprazole, fluoxetine, lisinopril, levofloxacin, zafirlukast, interferon, growth hormone, interleukin,

erythropoietin, granulocyte stimulating factor, nizatidine, bupropion, perindopril, erbumine, adenosine, alendronate, alprostadil, benazepril, betaxolol, bleomycin sulfate, dexfenfluramine, diltiazem, fentanyl, flecainid, gemcitabine, glatiramer acetate, granisetron, lamivudine, mangafodipir trisodium, mesalamine, metoprolol fumarate, metronidazole, miglitol, moexipril, monteleukast, octreotide acetate, olopatadine, paricalcitol, somatropin, sumatriptan succinate, tacrine, verapamil, nabumetone, trovafloxacin, dolasetron, zidovudine, finasteride, tobramycin, isradipine, tolcapone, enoxaparin, fluconazole, lansoprazole, terbinafine, pamidronate, didanosine, diclofenac, cisapride, venlafaxine, troglitazone, fluvastatin, losartan, imiglucerase, donepezil, olanzapine, valsartan, fexofenadine, calcitonin, and ipratropium.

11. The composition of claim 1 wherein the mean diameter of the microparticles is between about 1 and 5  $\mu\text{m}$ .

12. The composition of claim 1 wherein the microparticles are suspended in an aqueous solution suitable for parenteral administration.

13. The composition of claim 1 wherein the matrix is processed into tablets or capsules suitable for oral administration.

14. The composition of claim 1 wherein the matrix is formed into suppositories suitable for vaginal or rectal administration.

15. The composition of claim 1 wherein the matrix is in a dry powder form suitable for pulmonary administration.

16. A method for making a pharmaceutical composition comprising comprising a porous matrix formed of at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total surface area greater than about 0.5  $\text{m}^2/\text{mL}$ , and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0  $\text{g/mL}$  and having a total surface area of greater than or equal to 0.2  $\text{m}^2/\text{g}$ , comprising

(a) dissolving a drug in a volatile solvent to form a drug solution,

(b) combining at least one pore forming agent with the drug solution to

form an emulsion, suspension, or second solution,

(c) incorporating at least one excipient into the emulsion, suspension, or second solution, wherein the excipient is selected from the group consisting of hydrophobic and hydrophilic excipients which enhance dissolution rate, which stabilize drug in amorphous form by preventing crystallization, and which stabilize drug in crystalline form by inhibiting crystal growth, and

(d) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the porous matrix of drug and excipient.

17. The method of claim 16 wherein step (d) is conducted using a process selected from spray drying, evaporation, fluid bed drying, lyophilization, vacuum drying, or a combination thereof.

18. The method of claim 16 wherein the excipients are selected from the group consisting of polymers, amino acids, wetting agents, sugars, preservatives, pegylated excipients, tonicity agents, and combinations thereof.

19. The method of claim 16 wherein the matrix comprises between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution, stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

20. The method of claim 16 wherein the pore forming agent is a volatile salt.

21. The method of claim 20 wherein the volatile salt is selected from the group consisting of ammonium bicarbonate, ammonium acetate, ammonium chloride, ammonium benzoate, and mixtures thereof.

22. A method of delivering a drug to a patient in need thereof, comprising

administering to the patient a therapeutically or prophylactically effective amount of the drug in a formulation comprising at least one hydrophilic or hydrophobic excipient and microparticles of a drug, wherein the microparticles have a mean diameter between about 0.1 and 5  $\mu\text{m}$  and a total

surface area greater than about 0.5 m<sup>2</sup>/mL, and wherein the dry porous matrix is in a dry powder form having a TAP density less than or equal to 1.0 g/mL and having a total surface area of greater than or equal to 0.2 m<sup>2</sup>/g.

23. The method of claim 22 wherein the matrix comprises between 1 and 95% drug by weight in combination with at least one hydrophilic or hydrophobic excipient which enhances the rate of drug dissolution and stabilizes the drug in crystalline form by inhibiting crystal growth or stabilizes the drug in amorphous form by preventing crystallization.

24. The method of claim 22 wherein the formulation is suitable for administration by a route selected from the group consisting of parenteral, mucosal, oral, and topical administration.

25. The method of claim 24 wherein the parenteral route is selected from the group consisting of intravenous, intraarterial, intracardiac, intrathecal, intraosseous, intraarticular, intrasynovial, intracutaneous, subcutaneous, and intramuscular administration.

26. The method of claim 24 wherein the mucosal route is selected from the group consisting of pulmonary, buccal, sublingual, intranasal, rectal, and vaginal administration.

27. The method of claim 24 wherein the formulation is suitable for intraocular or conjunctival administration.

28. The method of claim 24 wherein the formulation is suitable for intracranial, intralesional, or intratumoral administration.

29. The method of claim 24 wherein the formulation is in an aqueous solution or suspension suitable for parenteral administration.

30. The method of claim 24 wherein the formulation is in a tablet or capsule suitable for oral administration.

31. The method of claim 24 wherein the formulation is in a suppository suitable for vaginal or rectal administration.

32. The method of claim 24 wherein the formulation is a dry powder suitable for pulmonary administration.

33. The method of claims 24 wherein the formulation is in a cream or

ointment suitable for topical administration.

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